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EXAMINER

DROESCH, KRISTEN L

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 03/15/2004

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/940,283

Applicant(s)

BARDY ET AL.

Examiner

Kristen L Droesch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-56, 58-147, 149 and 150 is/are pending in the application.
- 4a) Of the above claim(s) 3, 47-51, 60, 108-112 and 116 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 143, 144 and 146 is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-13, 15-46, 52-56, 58-59, 61-107, 113-115, 117-142, 145, 147, 149-150 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The drawings were received on 1/22/04. These drawings are approved.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 4, 16-18, 20, 23-25, 31, 39, 43, 47-48, 50, 52, 55-56, 59, 61, 71, 75-78, 82-83, 86, 92, 100 and 104 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams (5,601,607).

Regarding claim 1, Adams shows an ICD comprising a housing having a top surface (70n), a bottom surface (70a), a proximal end (74) and a distal end (76, 70c), wherein the housing is substantially bilaterally symmetrical along a length (left to right in Fig. 7) of the housing's top surface, and further wherein a width (top to bottom in Fig. 7) of the housing's top surface at the distal end of the housing is less than a width of the top surface at the proximal end of the housing; an electrical circuit (92) located within the main housing section; and an electrode (76, 84) electrically coupled to the electrical circuit and located on the distal housing section (Figs. 7-8).

With respect to claim 52, Adams shows a duckbill-shaped ICD having a housing comprising a main housing section (74) having a length, a width and a depth; a distal housing section (76, 84) extending distally from the main housing member, wherein the distal housing

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section is contiguous with the main housing section and has a width less than the width of the main housing section; an electrical circuit (92) located within the main housing section; and an electrode (76, 84) electrically coupled to the electrical circuit and located on the distal housing section (76, 84) (Figs. 7-8).

The term “duckbill-shaped” recited in the preamble has not been interpreted by the examiner to impart any additional structural limitations to the claim beyond those structural limitations recited in the body of the claim. See *Catalina Marketing International, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002).

Regarding claims 2, and 4, Adams shows at least a portion of the distal end (70c) and proximal end (74) is rounded (Figs. 7-8).

With respect to claim 16, Adams shows the proximal end (74) of the housing is contiguous with the distal end (76, 70c) of the housing (Figs. 1, 3, 8, and 11).

Regarding claims 17-18, Adams shows at least a portion (74) of the housing comprises an electrically nonconductive or insulated material (Col. 7, lines 13-23).

With respect to claims 20, and 82-83, Adams shows the housing and main housing section comprises a titanium alloy or stainless steel alloy (Col. 4, lines 7-8).

With respect to claim 23, Adams shows at least a portion of the electrode is non planar (rounded ends) (Figs. 7-8).

Regarding claim 24, Adams shows the housing is substantially planar (straight edges between rounded ends) (Figs. 7-8).

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Regarding claims 25, 31, 86, and 92, Adams shows the electrical circuit can provide cardioversion-defibrillation and the electrode (14, 14', 52, 62, 64, 66, 80) can emit energy for shocking the patient's heart (Figs. 11-12, 14-18) (Col. 5, line 43-Col. 6, line 45).

With respect to claims 39, and 100, Adams shows at least a portion of the electrode is non planar (rounded ends) (Figs. 7-8).

Regarding claims 43, and 104, Adams shows the electrode (76, 84) is substantially rectangular in shape (Figs. 7-8).

Regarding claim 55, Adams shows the implantable cardioverter is substantially bilaterally symmetrical along the length. The examiner points out that if a line of symmetry (from left to right in Fig. 7) was drawn down the center of the device, it is bilaterally symmetrical along the housings length as shown from left to right in Fig. 7.

With respect to claim 56, Adams shows the distal housing section is in fluid communication with the main housing section (Figs. 7-8).

Regarding claim 59, Adams shows the distal housing section (76, 84) has a distal end section and at least a portion of the distal end of the distal housing section is curved (Figs. 7-8).

With respect to claim 61, Adams shows the main housing section (74) has a proximal end and at least a portion of the proximal end of the main housing section is curved (Figs. 7-8).

Regarding claim 71, Adams shows the depth of the distal housing section (76, 84) is less than the depth of the main housing section (74) (Figs. 7-8).

With respect to claims 75-77, Adams shows at least a portion of the distal housing section and at least a portion of the main housing section is substantially non planar (the rounded ends of

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the distal and main housing sections) and at least a portion of the main housing section is substantially planar (the sides of the main housing section) (Figs. 7-8).

Regarding claim 78, Adams shows the distal housing section is substantially bilaterally symmetrical along its length. The examiner points out that if a line of symmetry (from left to right in Fig. 7) was drawn down the center of the device, it is bilaterally symmetrical along the housings length as shown from left to right in Fig. 7.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 5-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over (5,601,607). Adams discloses the claimed invention except for the specific dimensions of the housing. It would have been an obvious matter of design choice to form the width of the proximal end and the distal end of the housing to be from 1 cm to 10 cm wide or 2 cm to 5cm wide, the depth of the proximal end of the housing to be less than 15 mm, the depth of the distal end of the housing to be approximately 1 mm to 15 mm or 1 mm to 3 mm, and the length of the housing is approximately 3 cm to 30 cm long, or 5 cm to 20 cm long since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 UPSQ 237 (CCPA 1955).

6. Claims 15 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Meltzer (5,645,586). Adams is as explained before. Adams discloses the

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claimed invention except for the proximal end of the housing being hinged to the distal end of the housing, or the main housing section hinged to the distal housing section. Meltzer teaches a housing having hinges between sections of the housing, where the hinges provide the housing the ability to conform to and flex with the implantation site (Col. 2, lines 17-30). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a hinge as Meltzer teaches between the proximal end and the distal end of the housing, or the main housing section hinged to the distal housing section of Adams in order to for the housing the ability to conform to the implantation site and flex with the implantation site.

7. Claims 19 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) and further in view of Hassler et al. (5,470,345). Adams is as explained before. Although Adams fails to teach the housing or the main housing section comprises a ceramic material, attention is directed to Hassler et al., which teaches forming implantable medical devices from ceramic. Hassler teaches that the use of ceramics for the implantable medical device enclosure makes the enclosure transparent to RF waves for telemetry purposes. Hassler further teaches that metal enclosures often cause interference during telemetry (Col. 1, lines 19-27). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to form the housing or main housing section of Adams to comprise ceramic material as Hassler teaches in order to make the enclosure transparent to RF waves for telemetry purposes.

8. Claims 21-22, and 84-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) and further in view of Fayram et al. (5,658,321). Adams is as explained before. Although Adams fails to teach the housing or main housing member comprises an

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electrically insulated or non-conductive material, or a polymeric material, attention is directed to Fayram et al. which teaches an ICD that comprises an insulative, nonconductive, silicone polymer. Fayram et al. teaches coating a portion of the housing with silicone provides improved directionality for the defibrillation current. Therefore, it would have obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Adams to include a an electrically insulated or non-conductive material, or a silicone polymeric material as Fayram et al. teaches in order to provide improved directionality for the defibrillation current.

9. Claims 26-28, 30, 87-89, and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Mower (5,871,506). Adams discloses the claimed invention except for the setting forth the specific waveforms utilized in cardiac pacing. Mower teaches using biphasic (i.e. multiphasic) waveforms for cardiac pacing in order to improve cardiac conduction and contraction (Col. 2, lines 42-53). Mower also teaches that application of monophasic pacing pulses is well known, though it doesn't have the advantages of biphasic pacing pulses (Col. 6, line 23 – Col. 7, line 60). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply monophasic, biphasic (i.e. multiphasic) pacing pulses as Mower teaches with the device of Adams since they are well known in the art an the application of biphasic pulses provides the advantage of improving cardiac conduction and contraction.

10. Claims 27, 29, 88, and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Whigham et al. (4,821,724). Adams discloses the claimed invention except for the setting forth the specific waveforms utilized in cardiac pacing. Whigham et al. teaches the application of triphasic (i.e. multiphasic) pacing pulses so that

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reliable sensing of evoked responses can be sensed (Col. 2, line 63-Col. 3, line 1) due to the elimination of after potentials due to the charge balancing of the tri-phasic pulse (Abs).

Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply triphasic pacing pulses as Whigham et al. teaches with the device of Adams since the application of triphasic pacing pulses enables reliable sensing of evoked responses due to the elimination of after potentials due to the charge balancing of the tri-phasic pulse.

11. Claims 32-36, and 93-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) and further in view of Ostroff (5,215,081). Adams is as explained before.

Although Adams fails to specify the desirable ranges shock energy, attention is directed to Ostroff who teaches that the cardioversion-defibrillation energy is directly related to capacitance, shock duration, voltage, and resistance of the electrodes which in turn is dependent on electrode position and integrity (Col. 5, lines 50-56). It would have obvious to one with ordinary skill in the art at the time the invention was made to utilize the a ranges of shock energies set forth in the claims, since it is well known in the art that these factors are related to one another, and the ultimate energy delivered to the heart is dependent on these factors along with the resistance measured between the electrodes.

12. Claims 37-38, and 98-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Hauser et al. (5,385,574). Adams is as explained before.

Although Adams fails to teach the electrode can receive sensory information, attention is directed to Hauser et al which teaches a similar device with housing electrodes that can either be used for defibrillation or sensing (Col. 7, lines 9-15). Therefore it would have been obvious to

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one with ordinary skill in the art at the time the invention was made to configure the defibrillation electrode of Adams to be able to receive sensory information as Hauser et al teaches in order for the housing electrodes to be used interchangeably.

13. Claims 40-42, 44-46, 101-103, and 105-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607). Adams is as explained before. Adams discloses the claimed invention except for electrode being circular, ellipsoidal, square, triangular, thumbnail or spade shaped. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the shape of the electrode as taught by Adams with a circular, ellipsoidal, square, triangular, thumbnail or spade shaped electrode, since applicant has not disclosed that a circular, ellipsoidal, square, triangular, thumbnail or spade shaped electrode provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any shape electrode such as the rectangular electrode taught by Adams for applying defibrillation energy.

14. Claims 53-54, 62-63, and 72-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607). Adams discloses the claimed invention except for the specific dimensions of ICD. It would have been an obvious matter of design choice to form the width of the main housing section to be from 3 cm to 30 cm wide or 3 cm to 20cm wide, the depth of the distal housing section to be less than 15 mm, the depth of the main housing section to be approximately 1 mm to 15 mm or 1 mm to 10 mm, and the length of the housing is approximately 5 cm to 20 cm long or less than 30 cm long since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 UPSQ 237 (CCPA 1955).

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15. Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Laird et al. (6,445,956). Adams is as explained before. Adams discloses the claimed invention except for the distal housing section further comprising a shoulder region extending distally from the main housing section. Attention is directed to Laird et al. which teaches that along with designing implantable device of minimal volume intuitive considerations have led designers to avoid sharp corners on the exterior surface of implantable devices (Col. 1, lines 42-48). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a shoulder region on the distal housing section extending distally from the main housing section in order to avoid sharp corners on the exterior surface of implantable device.

16. Claims 65-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Laird et al. (6,445,956) as applied to claim 64. Adams and Laird et al. disclose the claimed invention except for the shoulder region having a width less than the width of the main housing section; the shoulder region width decreasing as the shoulder region extends distally from the main housing section; the shoulder region width decreasing proportionally as the shoulder region extends distally from the main housing section; the distal housing section further comprising a distal head that extends distally from the shoulder region and defines a distal end of the distal housing section; the distal head of the distal housing section has a width less than the width of the shoulder region; or the distal head of the distal housing section has a width greater than the width of the shoulder region of the distal housing section. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the shoulder region and distal housing section as taught by Adams and Laird et

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al. with the shoulder region having a width less than the width of the main housing section; the shoulder region width decreasing as the shoulder region extends distally from the main housing section; the shoulder region width decreasing proportionally as the shoulder region extends distally from the main housing section; the distal housing section further comprising a distal head that extends distally from the shoulder region and defines a distal end of the distal housing section; the distal head of the distal housing section has a width less than the width of the shoulder region; or the distal head of the distal housing section has a width greater than the width of the shoulder region of the distal housing section, since applicant has not disclosed that these particular shapes provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any shape of the shoulder region and distal housing section such as the shoulder region and distal housing section taught by Adams and Laird et al. for providing an implantable cardioverter defibrillator housing. A change in shape absent persuasive evidence of the significance of the configuration has been held to be a matter of obvious design choice to one with ordinary skill in the art. See *In re Dailey*, 357 F.2d 669 (CCPA 1966).

17. Claims 79-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Hauser (5,385,574). Although Adams fails to show at least a portion of the distal housing section comprises an electrically insulated or nonconductive material, attention is directed to Hauser, which shows a housing section (66) that is conductive and serves as an electrode like Adams with a portion comprising an electrically insulated or nonconductive material (Fig. 11, Col. 7, lines 9-25). Hauser teaches that the small region of insulation is utilized to isolate a small conductive region to serve as a return in a pacing or sensing

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configuration. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the distal housing section comprising a conductive surface serving as an electrode of Adams with a small region of insulation as Hauser teaches in order to isolate a small conductive region to serve as a return in a pacing or sensing configuration.

18. Claims 113-115, 117, 127-133, 139, 142, 145, 147, 149, and 150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Bardy (5,292,338).

Adams shows a method of inserting an ICD comprising providing a duckbill-shaped ICD comprising a housing (74,76, 84); an electrical circuit (92) located within the housing; an electrode (76, 84) located on the housing section (Figs. 7-8) and the ICD is configured to maintain the electrode in a predetermined relationship subcutaneously over a patient's ribcage (Fig. 3) (Figs. 7-8). Although Adams fails to specifically teach making a single incision on a patient's thorax and advancing the ICD through the single incision and subcutaneously over a patient's ribcage approximately between a patient's third and twelfth ribs, attention is directed to Bardy which teaches a similar ICD having an electrode located on the housing that is implanted subcutaneously over the ribcage through a single incision. Bardy teaches that since the housing acts as a defibrillation electrode, a single incision can be made to implant the electrode, compared to systems that require a separate subcutaneous electrode apart from the housing. Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to perform the steps of making a single incision on a patient's thorax and advancing the ICD through the single incision and subcutaneously over a patient's ribcage as Bardy teaches to the method of implanting the duckbilled ICD of Adams since the utilization of a

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single incision is facilitated by the use of a defibrillation electrode located on the housing and because a single incision is more advantageous than multiple incisions since a single making a single incision would reduces tissue trauma and bleeding.

The term “duckbill-shaped” has not been interpreted by the examiner to impart any additional structural limitations to the claim beyond those structural limitations recited for the structure of the housing.

Although Adams and Bardy do not explicitly state that the ICD is advanced approximately between a patient's third and twelfth rib, it is inherent that Adams and Bardy do so, since both state that the implant is located in the pectoral region, and Bardy specifically states that the implant is located in the left infraclavicular pectoral region. As seen in Fig. 2 of Sanchez, Zambrano (5,895,414) the clavicle (21) is located approximately at the same location or level as the third rib (23) in the pectoral region. Thus, if the ICD of Adams and Bardy is implanted through a single incision in the left infraclavicular pectoral region, it is advanced below the third rib and above the twelfth rib .

With respect to claim 114, Adams further shows the housing comprises a proximal end (74) and a distal end (76, 84), where the width of the distal end is less than the proximal end (Figs. 7-8).

Regarding claim 115, Adams shows at least a portion of the distal end (76, 84) is rounded (Figs. 7-8).

With respect to claim 117, Adams shows at least a portion of the proximal end (74) is rounded (Figs. 7-8).

Regarding claim 127, Adams shows the housing is bilaterally symmetrical along the housing's length (Figs. 7-8). The examiner points out that if a plane was located in regards to half of the depth, and along the length of the ICD, it is bilaterally symmetrical along the housings length.

With respect to claim 128, Adams shows the proximal end of the housing is contiguous with the distal end of the housing (Figs. 7-8).

Regarding claims 129-130, Adams shows at least a portion of the housing (74) comprises an electrically insulated or nonconductive material (Figs. 7-8).

With respect to claims 131-132, Adams shows the housing is substantially non planar (the rounded ends of the distal and main housing sections) and the housing is substantially planar (the sides of the main housing section) (Figs. 7-8).

Regarding claims 133, and 139, Adams shows the electrical circuit can provide cardioversion-defibrillation and the electrode (14, 14', 52, 62, 64, 66, 80) can emit energy for shocking the patient's heart (Figs. 11-12, 14-18) (Col. 5, line 43-Col. 6, line 45).

With respect to claim 142, Adams shows at least a portion of the electrode is non planar (rounded edges) (Figs. 7-8).

Regarding claims 145, and 147, Adams shows the ICD is advanced proximate the patient's heart and sternum (Fig. 3)

With respect to claims 149-150, Adams shows the ICD refrains from directly contacting the patient's heart and intrathoracic vessels. (Fig. 3)

19. Claims 118-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Bardy (5,292,338). Adams and Bardy disclose the claimed invention

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except for the specific dimensions of the housing. It would have been an obvious matter of design choice to form the width of the proximal end and the distal end of the housing to be from 1 cm to 10 cm wide or 2 cm to 5cm wide, the depth of the proximal end of the housing to be less than 15 mm, the depth of the distal end of the housing to be approximately 1 mm to 15 mm or 1 mm to 3 mm, and the length of the housing is approximately 3 cm to 30 cm long, or 5 cm to 20 cm long since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 UPSQ 237 (CCPA 1955).

20. Claims 134-136, and 138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Bardy (5,292,338) as applied to claims 113, and 133 and further in view of Mower (5,871,506). Adams and Bardy disclose the claimed invention except for the setting forth the specific waveforms utilized in cardiac pacing. Mower teaches using biphasic (i.e. multiphasic) waveforms for cardiac pacing in order to improve cardiac conduction and contraction (Col. 2, lines 42-53). Mower also teaches that application of monophasic pacing pulses is well known, though it doesn't have the advantages of biphasic pacing pulses (Col. 6, line 23 – Col. 7, line 60). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply monophasic, biphasic (i.e. multiphasic) pacing pulses as Mower teaches with the device of Adams and Bardy since they are well known in the art and the application of biphasic pulses provides the advantage of improving cardiac conduction and contraction.

21. Claims 135, and 137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Bardy (5,292,338) as applied to claim 113 and further in view of

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Whigham et al. (4,821,724). Adams and Bardy disclose the claimed invention except for the setting forth the specific waveforms utilized in cardiac pacing. Whigham et al. teaches the application of triphasic (i.e. multiphasic) pacing pulses so that reliable sensing of evoked responses can be sensed (Col. 2, line 63-Col. 3, line 1) due to the elimination of after potentials due to the charge balancing of the tri-phasic pulse (Abs). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply triphasic pacing pulses as Whigham et al. teaches with the device of Adams and Bardy since the application of triphasic pacing pulses enables reliable sensing of evoked responses due to the elimination of after potentials due to the charge balancing of the tri-phasic pulse.

22. Claims 140-141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Bardy (5,292,338) as applied to claim 113 and 139 and further in view of Hauser et al. (5,385,574). Adams and Bardy are as explained before. Although Adams and Bardy fail to teach the electrode can receive sensory information, attention is directed to Hauser et al which teaches a similar device with housing electrodes that can either be used for defibrillation or sensing (Col. 7, lines 9-15). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to configure the defibrillation electrode of the Adams and Bardy device to be able to receive sensory information as Hauser et al teaches in order for the housing electrodes to be used interchangeably.

Allowable Subject Matter

23. Claims 143-144, 146 are allowed.
24. The indicated allowable subject matter of claim 148 is withdrawn in view of Figure 2 of Sanchez-Zambrano, which illustrates the anatomy of the clavicle relative to the 3rd rib in the pectoral region. Rejections based on the newly cited reference(s) follow.

Response to Arguments

25. Applicant's arguments with respect to claims 1-2,4-13, and 15-47 have been considered but are moot in view of the new ground(s) of rejection.
26. Applicant's arguments with respect to claims 52-56, 58-59, and 61-107 have been fully considered but they are not persuasive.
27. Applicants argue that the main housing section (74) of the Adams ICD is not contiguous with the proximal housing section (76, 84). The examiner disagrees with this contention since the proximal housing section and distal housing section of the Adams ICD are in fact connected to each other. Furthermore, the insulating layer is continuous with the metal surface of the distal section of the housing and serves as the exterior surface of the distal section of the housing. Perhaps applicant would be more successful with this argument if the claim recited that the exterior surface of the distal housing section is contiguous with the exterior surface of the proximal housing section, in other words, the width of the exterior surface tapers from the main housing section to the distal housing section.

Applicants argue that Adams fails to teach an electrode located on the distal housing section and the distal housing section having a width less than the main housing member. Adams shows a distal housing section (76, 84), which has a width less than the main housing

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section and with an electrode (i.e. conductive surface) on the housing section. The fact that the conductive surface of the distal housing section (76, 84) serves as an electrode does not necessarily mean that the electrode is not *on* the distal housing section. The distal housing section comprises more than just the surface but includes the contents within the distal housing section.

Conclusion

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

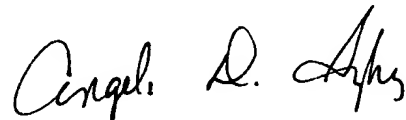
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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